PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference A02 P 2018 P	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/SE 03/01081	International filing date *(day/month/year)* 23.06.2003	Priority date *(day/month/year)* 22.07.2002
International Patent Classification (IPC) or both national classification and IPC A61B5/053		
Applicant ST JUDE MEDICAL AB et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
26.01.2004	01.09.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Schoeffmann, H Telephone No. +49 89 2399-2625

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/SE 03/01081

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-6 as published

Claims, Numbers

1-17 received on 20.08.2004 with letter of 19.08.2004

Drawings, Sheets

1/3-3/3 as published

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-17
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-17
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-17
	No:	Claims	

2. Citations and explanations

   see separate sheet

Concerning section V:

Document US-B-6 223 079 (hereinafter D1) is considered closest prior art in that it relates to a system which monitors congestive heart failure (CHF) by sensing impedance of the heart across any combination of the four heart chambers and determining impedance differences over time and comparing such differences to predetermined criteria (cf. D1, col.10, lines 10-52). D1 thus discloses the features as of the preamble of claim 1.

Claim 1 is distinguished over the prior art in that a quotient between the impedance maximum and minimum values during a cardiac cycle is determined and analysed to detect CHF. As these features are not known in the present context and by representing an alternative to the analysing methods known from the available prior art, claim 1 is considered to meet the requirements of Art.33 PCT.

Claims 2-17 likewise meet the requirements of Art.33 PCT in that these claims are dependent on claim 1.

CLAIMS

1. A congestive heart failure monitor comprising an impedance measuring unit (7; 30, 32) adapted to measure the impedance Z between at least two electrodes (2, 4; 6, 8; 10, 12; 17, 18; 20, 22, 24, 26) intended to be implanted in a patient such that a change in the left atrium volume results in a change of the measured impedance, and analysing means (7, 9; 36, 38, 40, 42, 44) for analysing said measured impedance for detecting an incipient congestive heart failure (CHF) **characterized** in that said analysing means comprise a quotient determining means (40) provided to determine the quotient between the impedance minimum and maximum values during a cardiac cycle, and in that said analysing means are adapted to analyse said quotient to detect CHF.

2. The monitor according to claim 1, **characterized** in that said analysing means comprise an averaging means (36, 38) provided to form a mean value of said measured impedance during a plurality of cardiac cycles, and in that said analysing mans are adapted to analyse said mean value to detect CHF.

3. The monitor according to claim 2, **characterized** in that a first comparison means is provided to compare said impedance mean value with a predetermined impedance threshold value, said analysing means being adapted to detect CHF from the result of said comparison.

4. The monitor according to claim 1, **characterized** in that said analysing means comprise quotient averaging means provided to form a mean value of said quotient during a plurality of cardiac cycles, and in that said analysing means are adapted to analyse said mean value to detect CHF.

5. The monitor according to claims 1 or 4, **characterized** in that a second comparison means is provided to compare said quotient or said mean value of the quotient with a predetermined quotient threshold value, said analysing means being adapted to detect CHF from the result of said comparison.

6. The monitor according to claim 3, **characterized** in that said averaging means is adapted to form a floating mean value of the measured impedance during a predetermined number of preceding cardiac cycles for use as said impedance threshold value.

7. The monitor according to claim 5, **characterized** in that said quotient averaging means are adapted to form a floating mean value of said quotient determined during a predetermined number of preceding cardiac cycles for use as said quotient threshold value.

8. The monitor according to any of the claims 1 – 7, **characterized** in that said analysing means are adapted to analyse said impedance mean value and said quotient to detect CHF.

9. The monitor according to claims 3 and 5, **characterized** in that said first and second comparison means are one and the same comparison means (42).

10. The monitor according to any of the preceding claims, **characterized** in that said electrodes (6, 8; 10, 12) are designed for implantation in the right and left atria, respectively.

11. The monitor according to any of the claims 1-9, **characterized** in that said electrodes (2, 4; 17, 18) are designed for implantation in the right atrium and left ventricle.

12. The monitor according to any of the claims 1- 9, said monitor being implantable, **characterized** in that one of said electrodes (18) is designed for implantation in the left atrium and the other electrode is formed of an outer capsule of the monitor.

13. The monitor according to any of the claims 10 - 12, **characterized** in that said electrodes (12; 18; 16) for implantation in the left atrium and the left ventricle are designed for implantation in a coronary vein.

14. The monitor according to claim 1, **characterized** in that said impedance measuring unit comprises a measuring circuit in the form of a synchronous demodulator for obtaining both the real and imaginary parts of the impedance (fig. 6).

15. The monitor according to claim 14, **characterized** in that said impedance measuring unit is adapted to determine the impedance phase angle and in that said analysing means are adapted to analyse the phase angle for detecting an incipient CHF.

16. A multisite heart stimulator, **characterized** by a monitor according to any one of the preceding claims.

17. The stimulator according to claim 16, **characterized** by a control unit provided to control the stimulation of the patient's heart in response to an output signal received from said monitor and representing the results of the analysis of the measured impedance, in order to optimize hemodynamics.
